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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,027	07/16/2003	Nai-Kong V. Cheung	#639-B-PCT-US	2089

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EXAMINER	
JOHNSEN, JASON H	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,027	CHEUNG, NAI-KONG V.	
	Examiner	Art Unit	
	Jason H. Johnsen	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *67-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Priority

Acknowledgment is made of applicant's assertion that the present application is a continuation in part of International application No. PCT/US02/01276, filed January 15, 2002, which claims benefit to a provisional application, serial number 60/261,911, filed January 16, 2001.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/17/2003, 7/14/2004, and 9/27/2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Drawings

This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

The specification is objected to because there is no "brief description of the drawings" section pursuant to the provisions of 37 CFR 1.74. Explanation of the drawings must be in this section and not scattered throughout the general disclosure. Appropriate correction is required.

Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 67, 80, 82-85 are rejected under 35 U.S.C. 102(b) as being anticipated by James et al. (US 5,849,720). Claim 67 discloses a composition comprising an effective amount of an orally administered glucan that is capable of enhancing efficacy of antibodies. Claim 80 further limits claim 67 by requiring that the composition be paired with a pharmaceutically acceptable carrier. Claim 82 further limits claim 67 by requiring the glucan to be of a high molecular weight moiety. Claim 84 further limits claim 67 by requiring the glucan to be derived from barley, oat, wheat or moss. Claim 85 further limits claim 67 wherein the glucan is stable to heat treatment.

B. James et al. teach a composition comprising an effective amount of orally administered glucan that is capable of enhancing efficacy of antibodies (see column 4, lines 54-64). James et al. teach the use of said composition paired with a pharmaceutically acceptable carrier (see column 5, example 1). James et al. teach glucan derived from yeast, bacteria, fungi, and plants (column 1, lines 13-15). James et al. teach the glucan to be of a high molecular weight ranging from 10,000 to 500,000 daltons (column 4, lines 23-25), which is stable to heat treatment (see Examples 1 and 2, column 5 and 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 68-79, and 83 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jamas et al (US 5,849,720), Dorothee Herlyn (US 5,130,127), Yan et al. (" Beta-glucan, a "specific" biologic response modifier that uses antibodies to target tumors for cytotoxic recognition by leukocyte complement receptor Type 3," Journal of immunology, 1999, Vol. 163, pp. 3045-3052), Dante J. Marciani (US 6,573,245), Cheever et al. (US 6,664,370), Chu et al. (Pub No. 2004/0109857), and Lane et al. (Pub No. 2003/0180254).

A. Claim 68 further limits claim 67 by requiring the antibody to be a monoclonal antibody. Claim 69 further limits claim 67 by requiring the antibody to be against cancer. Claim 70 further limits claim 69 by requiring the antibody to be a tumor-binding antibody. Claim 71 further

limits claim 70 by requiring the antibody to be capable of activating complement. Claim 72 further limits claim 71 by requiring the antibody to be capable of activating the antibody dependent cell-mediated cytotoxicity. Claim 73 further limits claim 70 by requiring the antibody to be directed to HER-1. Claim 74 further limits claim 70 by requiring the antibody to be directed to a ganglioside. Claim 75 further limits claim 74 by requiring the ganglioside to be GD2 or GD3. Claim 76 further limits claim 70 by requiring the antigen to be CD20 or CD22. Claim 77 further limits claim 70 by requiring the antigen to be HER-2/neu. Claim 78 further limits claim 70 by requiring the antigen to be CD25. Claim 79 further limits claim 69 by requiring the cancer to be a specific cancer listed therein. Claim 80 further limits claim 67 by requiring the composition be administered with a pharmaceutically acceptable carrier. Claim 82 further limits claim 67 by requiring a high molecular weight glucan. Claim 83 further limits claim 82 by requiring the molecular weight of the glucan range from 250,000 to 450,000 daltons. Claim 84 further limits claim 67 by requiring the glucan be derived from barley, oat, wheat or moss.

B. As in the 102b rejection discussed above, James et al teach the limitations of claim 67. Jamas et al. does not teach the limitations found in claims 68-72, and 79 as stated above. Dorothee Herlyn teaches a monoclonal tumor-binding antibody against cancer (column 1, lines 11-55), which is capable of activating complement (column 3, lines 40-45). Dorothee Herlyn teaches an antibody capable of activating the antibody dependent cell-mediated cytotoxicity (column 2, lines 25-30). Additionally, Dorothee Herlyn teaches the cancer to be melanoma or colon cancer (column 3, lines 55-57, claims 10 and 11).

C. As relating to claim 73, Dante J. Marciani teaches the antibody directed at HER-1 (column 12, line 54).

D. As relating to claim 74 and 75, Yan et al. teach the antibody directed to a ganglioside (page 12, middle paragraph, and page 14, last paragraph), and specifically, to ganglioside GD2 (page 12, middle paragraph).

E. As relating to claim 76, Chu et al. teach the antigen to be CD20 (page 15, paragraph 96 and table 4).

F. As relating to claim 77, Cheever et al. teach the antigen to be HER-2/neu (column 14, lines 47-57).

G. As relating to claim 78, Lane et al. teach the antigen to be CD25 (page 2, paragraph 25, and page 12, paragraph 133).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the above taught composition in an effective amount as taught by the applicant having the above-cited references before him. It is well known in the art that glucan works by activating the immune system in response to a myriad of factors, including many types of foreign cells and intigens--viruses, bacteria, and various types of cancer. Specifically, glucan mimics the natural physiologic response to an infectious challenge by enhancing the balanced, endogenous release of cytokines (James et al.). By considering the teaching of James et al. and Dorothee Herlyn, it would lead one skilled in the art to have a reasonable expectation of success in combining the method for producing high molecular weight, soluble glucan polymers taught by James et al. with the teachings of Dorothee Herlyn, Marciani et al, Yan et al., Chu et al., Cheever et al, and Lane et al. to treat infectious and autoimmune

diseases, including enhancing efficacy of antibodies against many types of cancer. One skilled in the art would be motivated to combine these two teachings to obtain a less evasive, more convenient cancer fighting regiment that included oral administration of tumor fighting agents, and thus overcome what was once a significant impediment in the art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 67, and the dependant claims that rely on it, 68-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims which depend from an indefinite claim are also indefinite. Ex parte Cordova, 10 U.S.P.Q.2d 1949, 1952 (P.T.O. Bd. App. 1989). The current claim language is drawn to an activity or desired property of a composition. This language does not particularly or distinctly provide sufficient clarity regarding the structural/formulaic/nomenclatorial identity of the chemical core applicants intend to represent as a component of the composition articulated in the claim. In the absence of specific description of what the amount to be administered orally is intended to accomplish, any amount of a glucan administered orally to accomplish any therapeutic result will suffice to meet this limitation of the claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason H. Johnsen whose telephone number is 571-272-3106. The examiner can normally be reached on Mon-Friday, 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason H. Johnsen
November 4, 2004

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623